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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,958	04/10/2002	Y. Tom Tang	PF-0675 USN	6628
7590	05/10/2004		EXAMINER	
Incyte Genomics Inc Legal Department 3160 Porter Drive Palo Alto, CA 94304			ZEMAN, MARY K	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

# Office Action Summary

## Application No.

09/914,958

## Applicant(s)

TANG ET AL.

## Examiner

Mary K Zeman

## Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

Claims 1-23 are pending in this application.

This application is a National Stage Application of an International Application, filed under the provisions of 35 USC 371, therefore, Lack of Unity practice is proper.

### ***Lack of Unity***

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

With respect to unity of invention PCT Rule 13.1 states:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Additionally, PCT Rule 13.2 states:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

With regard to the application of PCT Rule 13, 37 CFR §1.475 concerning unity of invention states:

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
  - (1) A product and a process specially adapted for the manufacture of said product; or
  - (2) A product and a process of use of said product; or
  - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
  - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
  - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Groups 1-22, claim(s) 1-2, 15, 16 drawn to a first product and first method of use of that product: a polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate group.

Groups 23-44, claim(s) 3-8, 10, 11, drawn to a second product and a first method of use of that product: a polynucleotide of ONE of SEQ ID NO: 23-44, each SEQ ID NO: is a separate group.

Groups 45-67, claim 4 drawn to a third product: an antibody that binds a polypeptide of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group.

Groups 68-90, claims 12-14, drawn to a second method of use of the polynucleotide of ONE of SEQ ID NO: 23-44, Each SEQ ID NO: is a separate Group.

Groups 91-113, claim 17 drawn to a method of screening for an agonist using a polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group.

Groups 114-136, claim 18 drawn to an agonist of a polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group

Groups 137-159, claim 19, drawn to a method of treatment with an agonist of a polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group.

Groups 160-182, claim 20 drawn to a method of screening for an antagonist using a polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group.

Groups 183-205, claim 21 drawn to an antagonist of polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group

Groups 206-228, claim 22, drawn to a method of treatment with an antagonist of a polypeptide of ONE of SEQ ID NO: 1-22, each SEQ ID NO: is a separate Group.

Groups 229-251, claim 23, drawn to a method of screening of a compound that alters expression of a nucleotide of ONE of SEQ ID NO: 23-44, EACH SEQ ID NO: is a separate Group.

**The inventions listed as Groups 1-251 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:**

**Each Group detailed above reads on a differing polynucleotide or polypeptide sequence. Each polypeptide is different from one another, and each have differing structural, biochemical and biological characteristics. Each polypeptide is different in form, structure, and composition from each polynucleotide. Each polynucleotide is different from one another, and from each polypeptide, as they have differing structural, biochemical and biological characteristics. Each agonist and antagonist are different from each of the polypeptides and polynucleotides in composition, structure and function. Each method of use is a distinct method having differing method steps, and goals. The special technical feature of each method is the steps set forth therein.**

**Further, SEQ ID NO: 1 is not a novel contribution over the art linking all the inventions, as set forth in the IPER for the related PCT Application. WO 99/22243 discloses SEQ ID NO: 215 having identity to SEQ ID NO: 1 and/or 23 and meeting the limitations of claims 1 and or 3. Therefore, Neither SEQ ID NO: 1 nor 23 are a novel contribution over the art linking all the listed inventions.**

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered** as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

**A responsive reply will comprise the election of a group, a specific recitation of the claims that read on that elected group, and a specific recitation of the SEQ ID NO: of that election.**


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Art Unit: 1631

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the contents of the electronic file wrapper, or on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
5/5/04  
A01631